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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,886	01/18/2000	Gale E. Smith	674506-2035.2	1236
20999	7590	06/22/2009	EXAMINER	
FROMMERM LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151		SRIVASTAVA, KAILASH C		
		ART UNIT		PAPER NUMBER
		1657		
		MAIL DATE		DELIVERY MODE
		06/22/2009		PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/484,886	SMITH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 March 2009.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 96-116 and 127-131 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 96-116 and 127-131 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/25/2009</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

1. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 25 March 2009 after a Final action was mailed on 20 February 2008. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 20 February 2008 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed 25 March 2009 has been entered. Accordingly an RCE has been established and the action on RCE follows.
2. Response and amendment filed 25 March 2009 further to Notice of Appeal filed 25 August 2008 to the Office Action mailed 20 February 2008 is acknowledged and entered.
3. In view of applicants' remarks and discussion filed 25 March 2009, applicants' remarks filed 29 June 2005 were reconsidered. In said remarks, applicants admit on record that the claimed "erythropoietin has an *in vivo* activity, however, the claimed activity of at least 200,000 U/mg, or at least 500,000 U/mg was obtained during *in vitro* testing" (See, Remarks filed 29 June 2005, Page 7, Lines 17-24) as stated at, e.g., paragraph 4a on Page 3 of the Menon Cox Declaration filed 24 March 2004. The following Office Action is based on re-consideration of Menon Cox's Declaration filed 24 March 2004 and remarks/discussion filed 25 March 2009.

### **Withdrawals In View of Amendments/Remarks**

4. In view of amendments to the Claims and remarks filed 25 March 2009 to the Office Action mailed 20 February 2008, following objections and rejection made to Claims 96-116 and 127-131 in the Office Action mailed 20 February 2008 are hereby withdrawn:

- Objection to Claims 97-116 and 127-31;
- Obviousness rejection to Claims 96-97, 99-116 and 130 under 35 U.S.C. §103(a) as obvious over Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) in view of Dorland's Illustrated Medical Dictionary (W.B. Saunders Co., Philadelphia, 1988, Page 581).

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### Claims Status

5. Claims 1-95 and 117-126 have been cancelled.
6. Claims 96-100, 111-116 and 127-131 have currently been amended.
7. Claims 96-116 and 127-131 are pending and are examined on merits.

### Information Disclosure Statement

8. The Information Disclosure Statement (i.e., IDS) filed 25 March 2009 is acknowledged has been made of record, considered and duly initialed sheet of the appropriate PTO form are enclosed with this Office Action.

Please note, however, the non-patent literature references cited on the enclosed PTO-1449 or equivalent with said IDS was incompletely recited on said PTO-1449 or equivalent, because said citations do not give all the details as noted in the instructions (i.e., Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published) in the NON-PATENT LITERATURE DOCUMENTS section of said form.

In order to expedite the prosecution, Examiner has completed the information regarding the Volume Number and issue Number for said reference on said PTO-1449 or equivalent.

### Objection to Claims

9. Following are new objections to Claims 97-116 and 127-131.
10. Claims 96-116 and 127-131 are objected to because of the following informalities:
  - As currently worded in amended Claim 96-98 and 127-131 the phrase, “(i) an *in vivo* activity” renders said claims incomprehensible, unclear and vague because the units for said activity are undefined in both Claims and in the specification. Appropriate correction/definition is required.
  - The dependency for Claims 97-116 is improper because the multiple dependent claims are dependent on a later Claim. Appropriate correction/clarification is required.

All other claims depend directly from the objected claims (e.g., Claim 99, 100 or 104) and are, therefore, also objected for the reasons set forth above.

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***Claim Rejections – 35 U.S.C. § 102***

11. The following is a quotation of 35 U.S.C. §102 which forms the basis for all anticipation rejections set forth in this Office action:

*A person shall be entitled to a patent unless –*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

12. Claims 96-97, 99-116 and 130 are rejected under 35 U.S.C. §102(b) as anticipated by Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) with evidence provided by Dorland's Illustrated Medical Dictionary (W. B. Saunders Co., Philadelphia, 1988, Page 581) for the reasons of record, especially the side by side comparison described in the table at Page 5 of the Office Action mailed 02 May 2007.

In response to art rejections under 35 U.S.C. §102(b) discussed *supra*, citing a number of case laws and applying said laws to the art rejection recited in the Office Action mailed 20 February 2008, applicants argue “Quelle et al. does not teach protein activity *in vivo*” because there is no experiment to determine or discuss *in vivo* erythropoietin protein activity” (See Remarks filed 03/25/2009, Page 8, Lines 24-27). Citing page 130, paragraph 2 of the Saghatelyan et al., reference, and referring to the Page 8, Section 6 of the Cox Declaration, applicants further conclude “the activity of a protein *in vitro* may differ greatly from its activity *in vivo*” (See, Remarks filed 03/25/2009, Page 8, Lines 28-32). Additionally, applicants “submit that the alleged admission on record that Quelle et al' purified recombinant erythropoietin has little, if any *in vivo* activity” was clearly intended to be used for the purposes of highlighting that Quelle et al does not provide *in vivo* evidence for protein activity” (See, Remarks filed 25 March 2009, Page 9, Lines26-29) .

First of all, applicants are not alleged to have made the statement on record that Quelle et al's purified recombinant erythropoietin has little in-vivo activity. Applicants indeed have admitted on record that Quelle et al's purified recombinant erythropoietin has little, *in vivo* activity (See Applicants' response filed June 25, 2003, Page 11, Lines 29-30). Applicants now argue that applicants' said statement on record was made merely to highlight that Quelle et al does not provide *in vivo* evidence for protein activity” (See, Remarks filed 25 March 2009, Page 9, Lines26-29) . Applicants can not argue both ways, unless applicants would like to change the statements of fact. Furthermore, in regard to applicants' arguments that nothing in the experimental methodology, results, or discussion sections in Quelle et al., demonstrates an experiment to demonstrate *in vivo* activity of Quelle et al's erythropoietin; the examiner would respectfully submit that still silence is not probative.

Quelle et al., are merely silent about an experimental methodology to demonstrate *in vivo* activity for their purified erythropoietin, wherein said erythropoietin clearly shows all of the features that are instantly claimed including the insect cell culture of *Spodoptera frugiperda* insect cells through baculovirus expression system to produce said erythropoietin activity.

Regarding the applicants' citation of Saghatelian et al., reference, to assert that the activity of a protein *in vitro* may differ greatly from its activity *in vivo*; (i)- Saghatelian et al., is not a prior art- reference and (ii) Saghatelian et al., reference is focusing more on genomic studies teaching about knock-out proteins and isoforms of proteins, yet Saghatelian et al., do not completely refute that the *in vitro* activity of a protein does not explain the *in vivo* activity of a protein. On the contrary, Saghatelian et al., teach that *in vivo* activities of many proteins have been successfully explained on the *in vitro* bases (See, Page 130, Column 1, Lines 34-37).

Applicants' arguments filed 25 March 2009 regarding the rejection to Claims 96-97 and 99-116 as anticipatory by Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) with evidence provided by Dorland's Illustrated Medical Dictionary (W.B. Saunders Co., Philadelphia, 1988, Page 581)) in the Office Action mailed 20 February 2008 have been fully and carefully considered but are not persuasive for the reasons of record in the Table at Page 5, Lines 17-28 in the Office Action mailed 02 May 2007, at page 4-5 items 11-12 of the Office Action mailed 20 February 2008 and those discussed *supra*.

## Conclusion

13. For the aforementioned reasons, no claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/  
Examiner, Art Unit 1657

Kailash C. Srivastava  
Patent Examiner  
Art Unit 1657  
(571) 272-0923

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657

16 March 2009